## Remarks

The undersigned again want to express his appreciation of the courtesies extended today during a personal interview. During the interview the invention was discussed along with the prior art, the previously pending claims and proposed claims.

Regarding the previously pending claims, the Examiner indicated that claim 9 would be allowable if rewritten as an independent claim and amended to change "adopted" to "fused". Claim 9 has been amended accordingly. Accordingly, claim 9 and claim 11 which depends therefrom are now allowable.

During the interview, applicant proposed new claims 16-32 which appear above, except that claims 31 and 32 have been presented in independent form. Claim 16 recites a method for producing a session treatment plan for fractionated radiation exposure of a patient following production of an inversely planned radiotherapy treatment plan based on dosage distributions for a target volume and organ that have been previously approved by a physician or physicist, comprising the steps of:

(a) using a more current image data set of a target volume of a patient and an organ of the patient to be protected to update the positions of the target volume and organ in a previously acquired image data set to obtain an updated image data set;

(b) using the previously approved dosage distributions to define constraints for volume-dosage histograms to be used to calculate a new session treatment plan for fractionated radiation exposure of the patient; and

(c) calculating the new session treatment plan using the constraints and the updated image data set.

Most of the discussion centered on exactly what is taught by the Swerdloff et al. patent, herein simply referred to as Swerdloff. The Examiner pointed to the text at column 3, lines 46-61, which reads as follows:

> Yet another object of the invention is to provide an interface that can be used to observe radiation delivered during a therapy session which can be used to alter radiation doses during later therapy sessions. By identifying the radiation entering and exiting a patient along each ray of a beam the radiation absorbed along each ray from each gantry angle can be identified and a post-treatment tomographic image associated with the patient slice can be provided. The human interface of the present invention can be used to observe the post-treatment tomographic image and compare the post-treatment image to the desired dose map to identify

> treatment errors. Where a treatment error (i.e. over or under radiation) has occurred, the error can be noted using the human interface and can be used to alter desired dose maps during later therapy sessions to compensate for the errors.

The Examiner particularly made reference to the "post-treatment tomographic image associated with a patient slice" and stated his belief that a post-treatment tomographic image is taken after an initial treatment and that such image is used as an updated tomographic image used for developing a later treatment plan based on an approved earlier plan. The undersigned disagreed with this interpretation and agreed to provide a comprehensive explanation of what is meant by the passage in question.

As will become apparent, Swerdloff says nothing at all about using a more current image data set of a target volume of a patient and an organ. Rather, a second tomographic image is only used to verify the patient set up.

> An image reconstructor 60 typically comprising a high speed array processor or the like receives the data from the data acquisition system 58 in order to assist in "reconstructing" a tomographic image from such data according to methods well known in the art. The image reconstructor 60 also communicates with computer 51 to assist in high speed computations used in the present invention as will be described below. The tomographic image allows verification of the patient setup just prior to radiation therapy treatment.

Column 6, lines 45-61. Nothing is said about obtaining a second image data set to update the locations of the target and protected organ prior to calculation of a second fractionated therapy plan.

As was pointed out during the interview, the "post-treatment tomographic image associated with a patient slice" referred to by Swerdloff is a tomographic absorption image generated from the radiation values detected by the detector array 50' and not from the data from the detector array 50 used by the tomographic imaging system 11. The tomographic imaging system 11 is used to generate the slice images on which the target and organs are outlined as illustrated in Figs. 16 and 17. The detector array 50' is used to generate a tomographic absorption image as illustrated in Fig. 20. This is explained further at column 17, lines 30-44:

> Referring also to FIG. 4, the radiation array detector 50' which is at all times opposite the radiation source 12, can be programmed to receive

> radiation from each of the rays within the fan beam at each gantry angle as radiation exits the patient 17. As described in U.S. Pat. No. 5,394,452, which issued on Feb. 28, 1995, the specification of which is incorporated herein by reference, the radiation values detected by the detector array 50' may be compared to the known values of radiation within each ray of the fan beam to determine the quantum of radiation absorbed within the patient along each ray of the fan beam from each gantry angle. The computer can use this data to generate a post-radiation tomographic image corresponding to each patient slice after a therapy session indicating the intensity of absorbed radiation within all regions of interest. (emphasis added)

Any confusion as to what Swerdloff meant by a "post-treatment tomographic image associated with a patient slice" can be resolved by looking at the patent referred to in the foregoing passage, U.S. Patent No. 5,394,452. As described in the '452 patent in the first paragraph of the summary, a verification system can be used in conjunction with a radiation intensity compensator to minimize the possibility of an uncontrolled beam ray irradiating nontumorous tissue. The verification system may collect tomographic data on absorbed radiation within the patient and generate tomographic absorption images therefrom. The tomographic absorption images may be used for radiation dose verification as well as for planning subsequent therapy sessions, these applications being the subject of Swerdloff's '733 patent. Consequently, the "post-treatment tomographic image associated with a patient slice" are radiation maps, i.e., maps showing the actual amount of dosage absorbed by the target and protected organ or organs along the image plane. (emphasis added)

This understanding is consistent with the manner in which the "post-treatment tomographic image associated with a patient slice" is used. Swerdloff states at column 17, lines 45-61:

> Referring to FIG. 20, after a therapy session, the operator can display each post-radiation tomographic image 160 on the display screen 132 separately to identify any radiation errors (i.e. deviation from the desired dose map). Unfortunately, despite sinogram iterations and dose map alterations to produce desired dose maps, it is often the case that an actual dose map may vary somewhat from a desired dose map. For example, referring to FIG. 21, often the circumferential area of a tumor or a distal peninsular area may receive less radiation than other portions. In hypothetical FIG. 20, 8 units have been delivered to the central portion of

> the tumorous area 122 whereas only 6 units have been delivered to the distal peninsular and outer portions of the tumorous area 122. In this situation, an operator can use the interface to display the post-radiation tomographic image 160 where radiation errors which occurred during a prior therapy session can be observed. (emphasis added)

According to Swerdloff, the radiation errors are used to automatically to modify the desired dose map to provide a compensated dose map for the next session. Thereafter, the operator then uses the interface used to generate the first plan to generate a second plan, as described at column 18, lines 25-44:

> By selecting the DOSE COMP function, the computer automatically mathematically combines the desired dose map and the actual dose map to provide the compensating new dose map to be used during the next therapy session. Again after this second dose map has been generated, the operator can use the interface to run a pre-radiation test therapy session generating a pre-radiation test tomographic image identifying likely dose dispersion the subsequent second therapy session. If the dose dispersion is acceptable, the second dose map can be saved in RAM and the operator can move on to observe other post-radiation tomographic images from the first therapy session to identify alterations required in the second therapy session. As above, the NEXT SC and PRE SC functions can be selected using the mouse to scroll back and forth between post-radiation tomographic images. When desired, the operator can select the EXIT function from the menu indicating to the computer that the operator wishes to exit the post-radiation image viewing mode.

Again it is noted that in the discussion of the next session, there is no mention of updating the positional image data of the target and organs to account for changes in the positions thereof.

For at least the reasons discussed above, allowance of claims 16-32 is respectfully requested.

As a final item, during the interview the Examiner's attention was directed to the PTO-1449 form listing the art cited in the International Search Report. The Examiner indicated consideration of four of the documents that were submitted. However, the Examiner drew a line through DE 199 12 708 for an unknown reason. The Examiner

indicated that upon re-submission of a PTO-1449 he will make the document of record in this case.

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, LLP

By _____
Don W. Bulson, Reg. No. 28,192

1621 Euclid Avenue
Nineteenth Floor
Cleveland, Ohio 44115
(216) 621-1113

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper or thing referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: October 9, 2003

_____
Don W. Bulson

H:\152\DWB\SCHW\P\P0145\P0145US.R03.wpd